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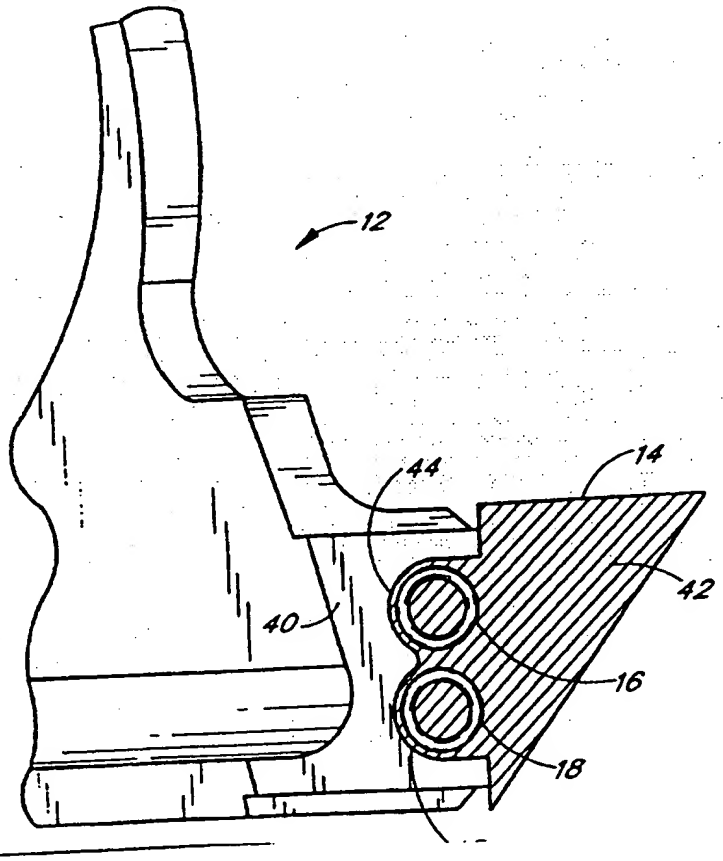
(54) Title: SEWING RING WITH INTEGRAL RETAINING SPRINGS

(57) Abstract

A sewing ring (14) of the present invention is used with an outer stent frame (12) to be mated with an inner stent (10) and tissue to form a tissue heart valve. The sewing ring (14) comprises an elastic ring (42) which is provided with a plurality of retaining springs (16, 18) which are encapsulated within a side of the elastic ring (42). This spring side of the elastic ring (42) is received in a corresponding plurality of grooves (44, 46) in a base of the outer stent frame (12) prior to the ultrasonic welding of a covering around the outer stent frame (12) and sewing ring (14). Preferably, the springs (16, 18) are formed into circles with spring ends (36, 38) joined via hooks formed by the last half coils of each end. The spring (16, 18) are preferably insert molded into the silicone elastomeric material of the elastic ring. The sewing ring and retaining springs configuration reduces the propensity of the retaining springs to uncouple, to translate circumferentially in the groove, and to vibrate against and damage the groove during the ultrasonic welding of the fabric covering. Thus, the optimum clamping force on the tissue placed between the inner and outer stents is maintained.



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SEWING RING WITH INTEGRAL RETAINING SPRINGS

Background of the Invention

This invention relates to the fabrication of bioprosthetic heart valve replacements. Valve replacements are required for patients having a heart valve which is diseased or otherwise incompetent. Commonly, heart valve bioprostheses are made from a combination of animal tissue and mechanical elements. These bioprostheses have an advantage over purely mechanical valves in that they do not require the use of anticoagulant therapy that plagues purely mechanical valves.

U.S. Pat. No. 5,163,955 (the '955 patent) discloses such a bioprosthetic valve, in which an inner stent, on which the tissue used to construct the valve is wrapped, is inserted into a spreadable outer stent containing a self-adjusting retaining spring around the circumference of its base. The inner stent posts are fitted with a plurality of outwardly-projecting pegs which register with holes cut in the tissue, and the inner stent assembly is covered with cloth. The spread outer stent clamps the stents together at its base and at a plurality of posts projecting from the bases of both the inner and outer stents. This clamping thus secures the tissue while compensating for irregularities and supplying a clamping force which is evenly distributed over the entire circumference of the tissue.

The outer stent disclosed in the '955 patent has an annular base constructed with a groove around its circumference, into which a self-adjusting retaining means such as a garter spring is fitted. The garter spring provides a clamping force when the inner stent is inserted into the outer stent. Additionally, the posts on the outer stent are configured with windows surrounded by struts, which give shape to the post. The window is shaped to conform to the shape of the inner stent posts while leaving a small gap between the inner stent posts and the struts when the inner stent is inserted into the outer stent. Such an arrangement facilitates the insertion of the inner stent into the outer stent and provides for a uniform application of the clamping force to the tissue.

At the bottom of each of the windows in the outer stent posts are slots which segment the base into a plurality of arcuate portions. The slots enable the outer stent to be spread open so that it can easily be fitted over the inner stent without damaging the tissue during the valve assembly process.

An elastomeric sewing ring is attached to the base of the outer stent assembly to facilitate the sewing of the assembled heart valve into the patient. The entire

assembly is covered with a fabric cover, typically made out of DACRON, which is bonded to the bottom of the outer stent base.

The current assignee's international application entitled STENTS FOR AUTOLOGOUS TISSUE HEART VALVE, published as W0 95/16412 on June 22, 1995, discloses the provision of two retaining springs disposed around the circumference of the base of the outer stent to prevent the inner and outer stents from becoming unsecured if one of the springs breaks. A separate elastomeric sewing ring is positioned over the springs and around the base of the outer stent. Each retaining spring is a conventional toroidal-shaped spring which wraps around the base of the outer stent and the two ends of each spring connect at a spring joint where the two ends are screwed together.

However, since the fabric cover is thermally bonded to the outer stent by an ultrasonic welding process, the welding process can cause the springs to vibrate significantly and become uncoupled from the base of the outer stent. Moreover, determining when a spring has uncoupled is problematic since the spring is hidden by the DACRON covering. Thus, x-rays of the valve may be necessary to determine if the springs uncoupled. Furthermore, the vibrations from the welding process may cause the springs to rotate circumferentially around the base of the outer stent, thereby possibly moving the spring joint into one of the gaps in the base.

Summary of the Invention

In accordance with the present invention, an improved sewing ring is provided which is disposed around the base of an outer stent of a tissue heart valve for clamping the outer stent to an inner stent and to facilitate the sewing of the assembled heart valve into the patient. The inner and outer stents cooperate to form a heart valve implanted into a patient, typically by the use of sutures. The present invention provides a sewing ring and retaining springs configuration which lessens or eliminates the propensity for the retaining springs to uncouple during the process of welding a fabric covering to the outer stent.

Preferably, the outer stent has a base including a plurality of slots. In one preferred embodiment, an elastic sewing ring is disposed around the base where an upper retaining spring and a lower retaining spring are incorporated into the elastic sewing ring by an insert molding or other suitable method. By expanding the elastic sewing ring, the sewing ring is placed over the base of the outer stent, thereby

providing a secure fit to the base. Alternatively, the sewing ring may be bonded to the base. The sewing ring may be made of silicone elastomer, and the sewing ring may have a generally triangular cross-section. The base of the outer stent is preferably constructed with a pair of grooves around its circumference, into which the upper and lower retaining springs within the sewing ring are fitted to act as a clamping force.

The provision of more than one retaining spring is an advantageous feature of the present invention which gives the valve redundancy, for if one spring breaks, another will continue to provide the outer stent's clamping force on the inner stent. However, the present invention may be used with only one retaining spring insert molded into the silicone sewing ring as well.

The incorporation of the retaining springs within the silicone sewing ring provides the advantage of holding the upper and lower retaining springs in place within the grooves and preventing the springs from uncoupling during the ultrasonic welding process. Furthermore, since the springs are encapsulated within the sewing ring, the springs do not damage the grooves of the base by vibrating against the grooves during the ultrasonic welding process. Having the springs insert molded into the sewing ring dampens the spring vibration during welding so that the springs do not damage the grooves. Also, the springs are encapsulated so that the elastic material of the sewing ring is placed inside the coils of the springs to take away any vibration of the springs during the welding process.

Another feature of the present invention which prevents the retaining springs from uncoupling at the spring joint is a reconfiguration of the end coils on each retaining spring so that the end coil loops are transverse to each other, ensuring that the spring ends remain coupled together. The last-half coil of each end of the spring is bent outward to form a hook, and then the two ends may be hooked together. Then, the gaps in the hooks may be closed to ensure that the spring does not uncouple.

Brief Description of the Drawings

FIGS. 1a and 1b are side views of the spring joint used in the prior art for heart valves.

FIG. 2 is side view of an alternate spring joint used in the prior art for heart valves.

FIG. 3 is a side view of the spring joint of the retaining spring of the present invention.

FIG. 4 is a cross-sectional view of the sewing ring with integral retaining rings of the present invention.

FIG. 5 is a partial cross-sectional view of a portion of an outer stent of the present invention showing the sewing ring fastened to the outer stent.

FIG. 6 is an exploded view of an outer stent having a sewing ring with features of the present invention.

FIG. 7 is a perspective view of mated inner and outer stents using a preferred embodiment of a sewing ring of the present invention.

Detailed Description of the Preferred Embodiments

Inner and outer stents of the tissue heart valve have frames 10, 12, respectively constructed out of a thermoplastic material such as DELRIN or the like using injection molding to form the entire component using unibody construction techniques, instead of welding or the like to attach any protuberances. Unibody construction minimizes risk to the patient when compared to welding, since welded bonds can break more easily, leading to the injection of valve components or fragments into the bloodstream.

Once constructed, the outer stent frame 12 is integrated with other components, including the sewing ring 14 of the present invention which has a plurality of retaining springs 16, 18 incorporated within, and both frames are covered with a fabric 20 such as DACRON or the like, to form the completed inner and outer stents 10, 12 used in the valve assembly. FIG. 7 shows the mated stents without the tissue or fabric coverings.

Figures 1a, 1b and 2 illustrate prior art spring joints where left and right ends of the spring are twisted together to form a ring. Figures 1a and 1b show a five turn interconnect where left end 22 and right end 24 are twisted together to form a spring joint 26. Figure 1a shows two and one-half coils of both the left end 22 and the right end 24 overlap each other at the spring joint 26, forming a five coil overlap. Similarly, Figure 2 shows a six turn interconnect where three coils of left end 28 and right end 30 are twisted together to form spring joint 32. These spring connections as well as similar ones are familiar to those of skill in the art.

Figure 3 illustrates the improved spring joint 34 of the present invention which prevents the springs 16, 18 from uncoupling. Preferably, the springs are

formed into circles with spring ends 36, 38 joined via hooks formed by the last half-coils of each end. As shown in Figure 3, the last half-coil of left end 36 has been twisted from its conventional direction to form a hook, as has the last half-coil of right end 38 of the springs 16, 18. Since ends 36 and 38 have been oriented so that their directions are transverse to each other, their orientations are used to form the spring joint 34 illustrated in Figure 3. Left end 36 and right end 38 are subsequently closed to prevent the joint 34 from uncoupling.

Figure 4 illustrates a cross-sectional view of the sewing ring 14 with integral retaining springs 16, 18 of the present invention. Figure 5 illustrates how the sewing ring 14 is fastened to the base 40 of the outer stent 12. As shown in Figure 4, upper retaining spring 16 and lower retaining spring 18 are embedded within the silicone rubber sewing ring 14 by an insert molding or other suitable forming method known to those of skill in the art. The elastic material 42 that comprises the sewing ring 14 is also located between the spring coils of springs 16 and 18 thereby providing different retaining force characteristics than using two independent springs surrounded by a separate sewing ring, and also reducing spring vibration during the welding process. The cross-section of sewing ring 14 is generally triangular in shape. While this is the preferred configuration, many other configurations are also possible as will be apparent to one skilled in the art. The springs 16 and 18 are positioned within sewing ring 44 closer to one side of the sewing ring 44 to ensure that springs 16 and 18 will be able to exert sufficient clamping force against the base 40 of the outer stent 12. Springs 16 and 18 are fitted within grooves 44 and 46, respectively, of the base 42.

Since the springs 16 and 18 are integral to the elastic sewing ring 14, the vibrations caused by an ultrasonic welding process used to thermally bond the fabric cover 20 to the outer stent 12 do not cause the spring joint 34 to uncouple. Furthermore, springs insert molded as shown in the present invention do not translate circumferentially into undesirable areas, i.e., in the gaps along the base 40 of the stent 12 where the joint 34 would be left unsupported, on the outer stent 12 during ultrasonic welding. With the present invention, even if the spring joints were to translate into gaps, the joints 34 would not become misaligned or uncoupled because the joints 34 would still be restrained from twisting by the elastic sewing ring 14. Having the spring joint 34 uncouple or become misaligned is undesirable since a less than optimum clamping force will be exerted on the tissue between the

stents.

FIG. 6 shows the sewing ring 14 along with the outer stent frame 12 and covering 20 to be used therewith. The sewing ring 14 is positioned about the base 40 of the outer stent frame 12 and then the covering 20 emplaced about the frame 12 and sewing ring 14. The completed outer stent is then ready to be mated with the inner stent 10, in the manner shown in FIG. 7.

While embodiments and applications of this invention have been shown and described, it should be apparent to those skilled in the art that many more modifications are possible without departing from the scope of the present invention.

WHAT IS CLAIMED IS:

1. A sewing ring for a tissue heart valve having an inner stent and an outer stent, said outer stent having a base with a plurality of grooves for receiving said sewing ring, said sewing ring comprising:

an elastic ring disposed around said base for allowing the securing of said outer stent to a patient; and

a plurality of retaining springs, each having a first end and a second end and comprised of a series of coils, said retaining springs being encapsulated within said elastic ring for securing said outer stent to said inner stent;

wherein each of said retaining springs has a spring joint formed by hooking a last half-coil of said first end of said spring with a last half-coil of said second end of said spring.

2. A sewing ring for a heart valve having an inner stent and an outer stent, said outer stent having a base with a groove for receiving said sewing ring, said sewing ring comprising:

an elastic ring for attachment to said base of said outer stent, said elastic ring allowing said valve to be secured to a patient; and

a retaining spring formed in a circle and encapsulated within said elastic ring for securing said outer stent to said inner stent, said spring positioned at a side of said elastic ring to be received in said groove, said encapsulation reducing the likelihood of said spring uncoupling from its circular configuration and thereby maintaining optimum clamping force between said outer stent and said inner stent.

3. The sewing ring of Claim 2, wherein said spring has a first end and a second end, said spring comprising a series of coils so that said circular configuration is formed by hooking a last half-coil of said first end with a last half-coil of said second end of said spring.

4. The sewing ring of Claim 2, wherein said elastic ring is formed of a silicone elastomer.

5. The sewing ring of Claim 4, wherein said spring is insert molded into said elastic ring.

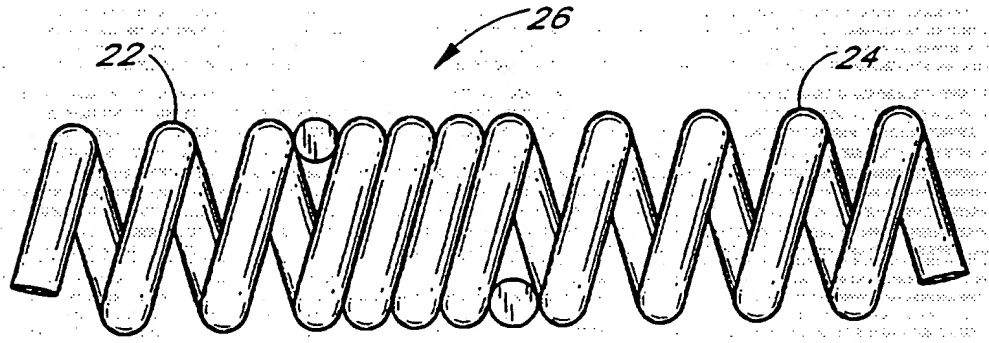

FIG. 1a
(PRIOR ART)

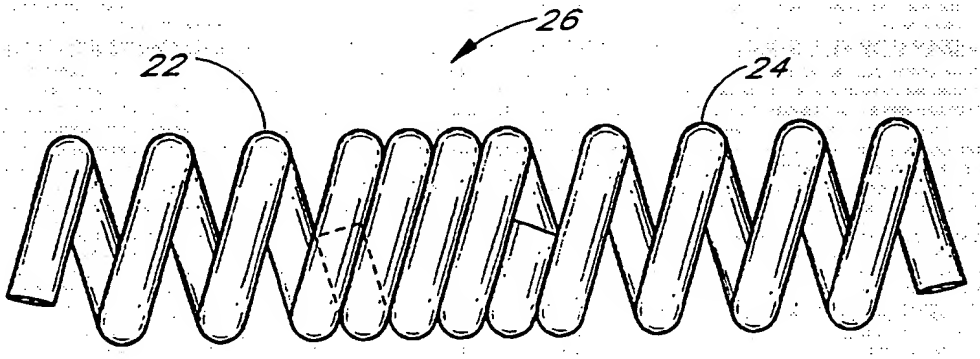

FIG. 1b
(PRIOR ART)

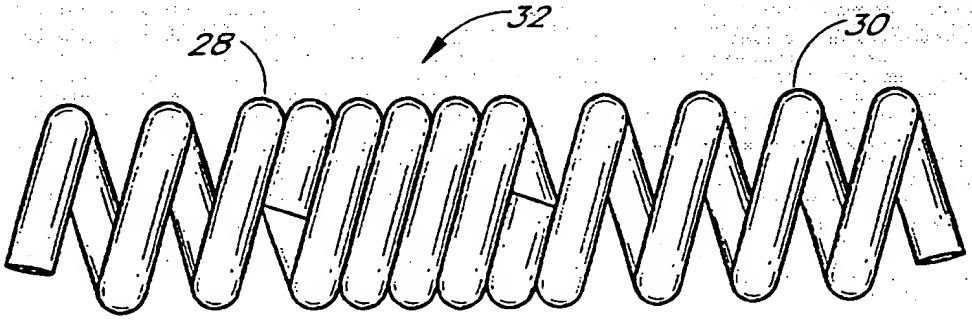

FIG. 2
(PRIOR ART)

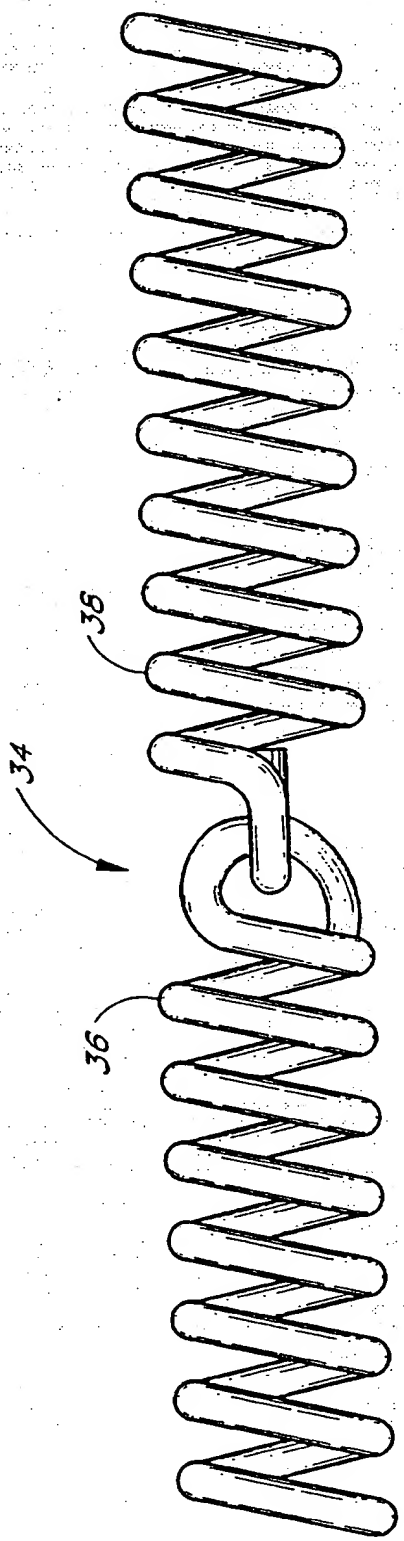

FIG. 3

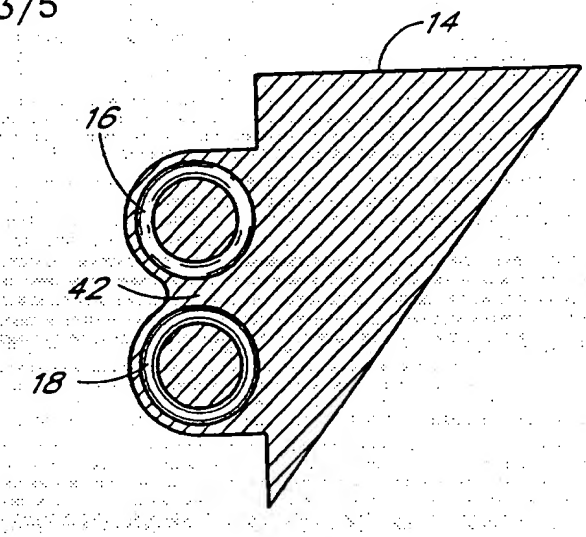

FIG. 4

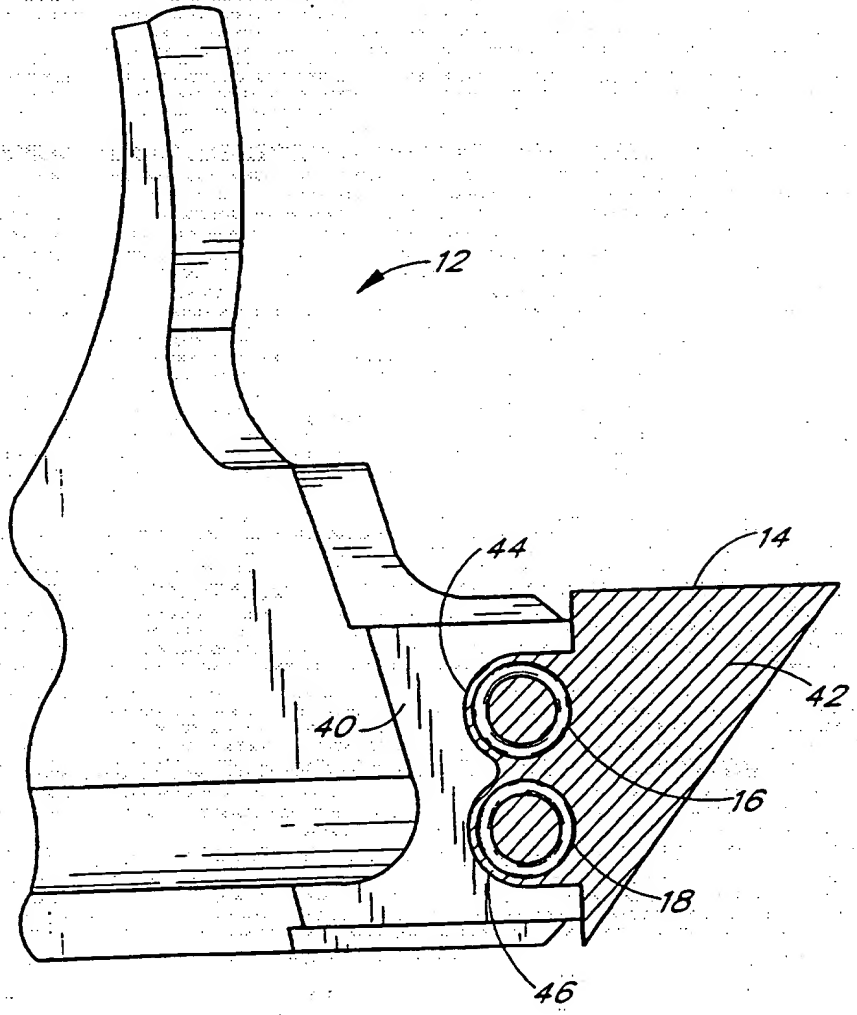

FIG. 5

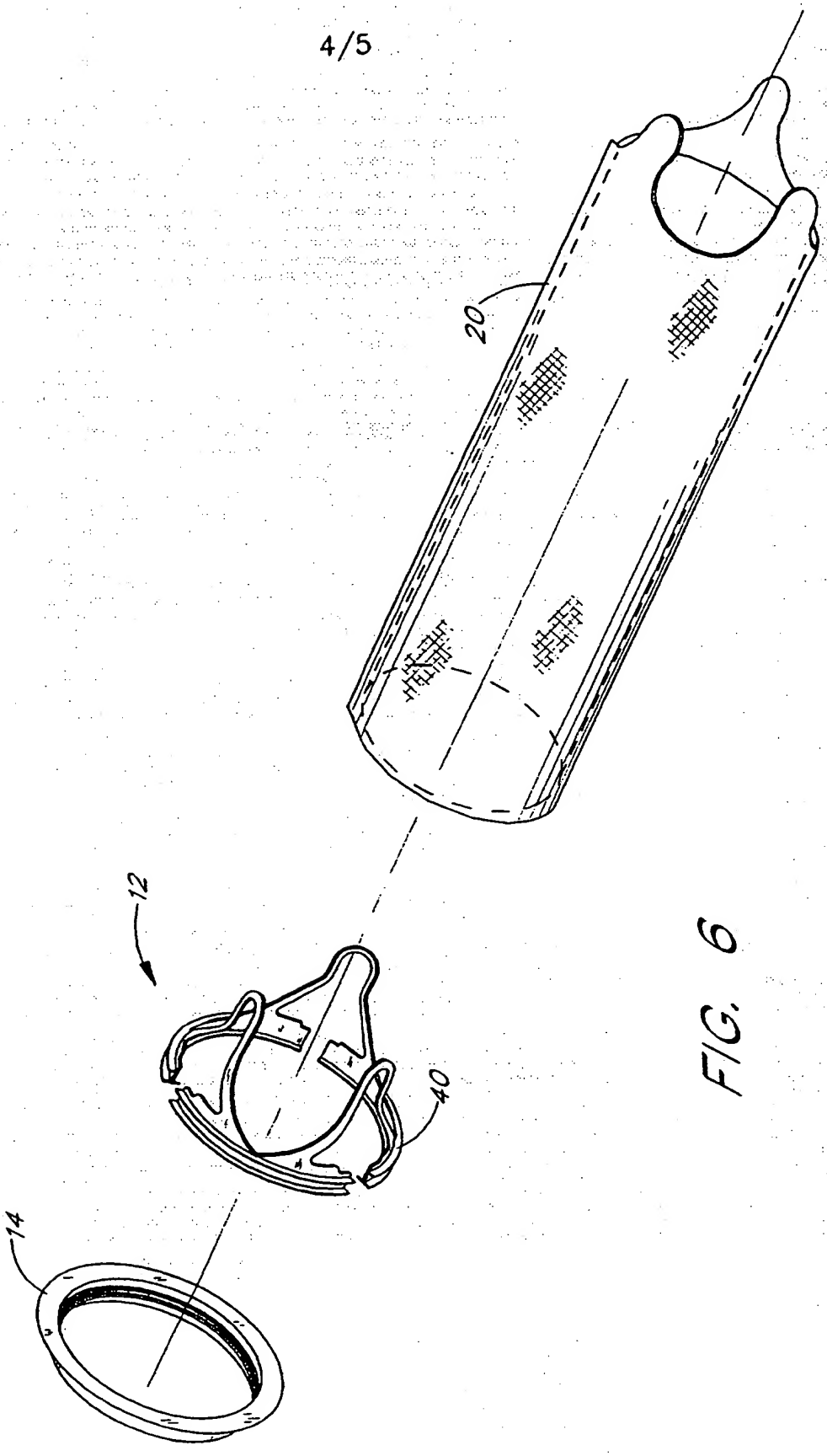

FIG. 6

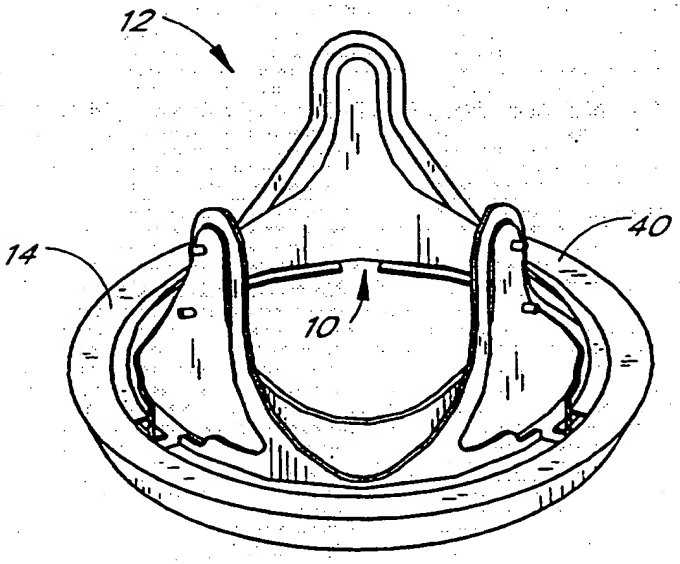

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/15026

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/04; A61F 2/24
US CL :606/148; 623/2
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/148, 623/2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,163,955 A (LOVE et al) 17 November 1992, col. 11, lines 43-49, and 63-68; and col. 12, lines 1-7.	2, 4

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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